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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR CONFIRMATION NO. ATTORNEY DOCKET NO. 10/606,575 06/26/2003 David Edgren ARC3234R1 4693 **EXAMINER** 27777 7590 05/23/2006 PHILIP S. JOHNSON AHMED, HASAN SYED **JOHNSON & JOHNSON** ART UNIT PAPER NUMBER ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 1615 DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) |
|---|---|--|------------------------------|
| | | 10/606,575 | EDGREN ET AL. |
| | Office Action Summary | Examiner | Art Unit |
| | | Hasan S. Ahmed | 1615 |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | |
| Status | | | |
| 1) | Responsive to communication(s) filed on | · | |
| 2a) <u></u> □ | This action is FINAL . 2b)⊠ This | s action is non-final. | |
| 3) | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | |
| Disposition of Claims | | | |
| 4)⊠ Claim(s) <u>1-29</u> is/are pending in the application. | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | |
| 5) Claim(s) is/are allowed. | | | |
| 6) Claim(s) is/are rejected. | | | |
| 7) Claim(s) is/are objected to. | | | |
| 8) Claim(s) 1-29 are subject to restriction and/or election requirement. | | | |
| Application Papers | | | |
| 9) The specification is objected to by the Examiner. | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | |
| Priority under 35 U.S.C. § 119 | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | |
| Certified copies of the priority documents have been received. | | | |
| 2. Certified copies of the priority documents have been received in Application No. | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | |
| | | | |
| Attachment(s) | | | |
| | e of References Cited (PTO-892) se of Draftsperson's Patent Drawing Review (PTO-948) | 4) Interview Summary Paper No(s)/Mail D | |
| 3) Infor | mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date | | Patent Application (PTO-152) |

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24, drawn to a controlled release composition, classified in class

424, subclass 465.

II. Claims 25-29, drawn to an oral dosage form, classified in class 424,

subclass 465.

The inventions are distinct, each from the other for the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that

they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In

the instant case Group I is directed to a controlled release composition with no core

structure while Group II is directed to an oral dosage form with a core structure.

Because these inventions are independent or distinct for the reasons given

above and the inventions require a different field of search (see MPEP § 808.02),

restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct

species:

Species I - Election of dosage form in claims 19 and 20:

a. Matrix system

b. Osmotic system

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 40 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Should Applicant traverse on the ground that the inventions or species are not

patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection

under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-

4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL P. WOODWARD SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600